DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO
6530/7
Ser 273/0055
21 Jun 02

Dockets Management Branch (HFA-305)
Food and Drug Administration
563 Fishers Lane
Room 1061
Rockville, MD 20852

SUBJECT: COMMENTS ON DRAFT GUIDANCE FOR STREAMLINING THE DONOR INTERVIEW PROCESS (DOCKET NUMBER 02D0080)

To Whom It May Concern,

The Food and Drug Administration has recognized and is providing a needed service to the blood industry with the guidance proposed in "Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires (Draft Guidance)". Upon review, the Navy Blood Program (NBP) wishes to submit comments for consideration in preparing the final guidance:

Comment 1. It has been the Navy's long-time experience that self-administration of the health history questionnaire has been efficient and effective as evidenced by our post donation biological product deviation (BPD) reports over the last years: 4:89 or 4% (1999), 5:48 (10%) 2000, and 7:93 (8%) 2001. We applaud the agency's proposed change to allow the self-administration of the high risk questions. This single change will improve donor throughput and reduce donation time significantly.

Comment 2. The NBP requests the FDA consider defining in the final guidance the phrase, "on the day of donation" (page 3, paragraph III.A.2.) with a more liberal interpretation of "within 24 hours of donation". This interpretation would allow donor center personnel to pre-screen donors and schedule donations within the 24-hour time limit. While it should in no way impact on blood safety, it would greatly improve collection efficiency and reduce or eliminate time wasted in searching for last minute replacement apheresis donors.

This interpretation would allow pre-screening whole blood donors against standard operations procedures in a no-pressure environment, up-front elimination of donors who do not meet donation criteria, and more precise scheduling of eligible donors. This one action would improve donor throughput, decrease donor screening deviations, allow for greater donor interview confidentiality and discussion without peer and production pressure, and decrease BPDs resulting from failure to meet time

limitations. Donor satisfaction should also improve with greater attention at interview, if needed, and faster throughput at donation for eligible donors.

Comment 3. The NBP respectfully disagrees with the recommendation for manual procedures on page 3, paragraph III.A.4 that states "You should not allow new donors to self-administer the donor questionnaire." Again, it has been the NBP's experience that first-time donors are extremely attentive to all the procedures involved in the donation process. Allowing them to see, read, and answer donor questions for the first time in a self-paced, focused, manner allows them time to reflect on their answers rather than pressuring them to answer critical questions at a pace set by an experienced interviewer who may be pressured for time.

Implementation of the requirement to perform complete one-on-one health history interviews with first-time donors will severely impact military donor programs whose donor pools consist of 65-75% first-time donors. Staffing to meet such a requirement on a mobile drive with a goal of 35-50 units would increase the on-site collection time and jeopardize the staff's ability to return to the center and manufacture components within the required time limits.

The NPB contends the final impact of this *front-loaded* time requirement could very likely be: donors turned away for lack of time to collect, wasted blood products for lack of time to process, and increased BPDs for deviations in manufacturing because of time pressures that can not be met. The NBP BPD statistics do not support a need to implement such a requirement and perceives this requirement would have a critically adverse impact on collections and ultimately reduce the availability of blood and blood products to the military community.

The NBP would like to thank the FDA for the opportunity to comment on the draft guidelines and trusts that the FDA will find the points addressed to be of value.

Points of contact for this matter are Ms. Jan Sigmon, Quality Assurance Manager, Navy Blood Program, or myself at (202) 762-3434.

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Sincerely,

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Medical Service Corps
United States Navy
Deputy Director, Navy Blood Program
By direction of the Chief,
Bureau of Medicine and Surgery

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